# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/663,749 | 09/17/2003 | Tadashi Tanabe | Q77569 | 5604 |

23373 7590 08/24/2005

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

| EXAMINER | |
|---|---|
| KIM, YUNSOO | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/663,749 | TANABE ET AL. | |
| | Examiner | Art Unit | |
| | Yunsoo Kim | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/19/03,4/4/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Claims 1-20 are pending.

2. Applicant's election without traverse of Group III, drawn to claims 13-20, in the reply filed on 7/13/05 and the request to rejoinder non-elected method claims upon allowance of the product claims are acknowledged.

Accordingly, claims 1-12 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected invention.

Therefore, claims 13-20 read on antibody to SEQ ID NO:18 are under consideration in the instant application.

3. Applicants' IDS filed on 12/19/03 and 4/4/05 have been acknowledged. However, the consideration of references is limited to Ngo reference from 12/19/03 and Weksler reference from 4/4/05 as Applicants failed to provide the rest of the references.

4. Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the parent applications (08/579,706, 09/037,758, and 09/670,582) which priority is claimed upon fail to provide adequate written support under 35. U.S.C.112 for the limitation (SEQ ID NO:18) recited in claims 13-20 of this application 10/663,749. Thus, the US priority date is deemed 9/17/03.

5. Applicant is required to update US priority in the first line of the specification and update status of all pending applications. It is noted a typographical error on the serial number of parent application.

6. The following is a quotation of the second paragraph of 35 U.S.C.112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) The phrase " immunological activity" recited in claim 13 is ambiguous and unclear and the metes and bounds of the claimed "immunological activity" is not defined.

(B) The term "part" recited in claim 13 is not defined.

(C) The phrase "substantially depicted" recited in claim 13 and the term "depicted" recited in claim 17 are ambiguous and unclear and the metes and bounds of the claimed limitation is not defined.

(D) The phrase "part ...of an amino acid sequence" recited in claim 13 is ambiguous as it may mean "a part of SEQ ID NO:18 as small as 2 amino acid residues".

For examining purpose, the phrase "substantially depicted" is recognized as to mean "comprising" because the p. 7. [38] defines the "substantially" to include deletion, substitution, or addition as long as the polypeptide has immunological/biological activity similar to the PGIS.

The term "part" is recognized as to mean "fragment".

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out this invention.

9. Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody specifically binds to the amino acid sequence consisting of SEQ ID NO:18, does not reasonably provide enablement for any antibody comprising "part" of SEQ ID NO:18 as recited in claims 13 or any antibody "substantially depicted" in SEQ ID NO:18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without any undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The phrase "part of SEQ ID NO:18" in claims 13 has not provided sufficient information that distinctly identifies any antibodies other than the antibody specifically binds to the amino acid consisting of SEQ ID NO:18. The specification fails to provide sufficient guidance and direction as to how the skilled artisan can make such antibodies commensurate in scope with the claimed invention. The specification fails to provide any guidance on how to make and use the antibodies to any amino acid sequence similar to SEQ ID NO:18 and fragments thereof.

Coleman et al. (Research in Immunology, 1994; 145(1): 33-36) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding. As is evidenced in p. 38 [175-176], antibody against human PGIS did not reacted with bovine PGIS. Miyama et al. (Biochem. Biophy. Res Comm. 1994, 200; 1728-1734, abstract) teach the human PGIS and bovine PGIS share 88% sequence identity.

Therefore, there is insufficient direction as to how to make and to use any antibodies to polypeptides substantially depicted in SEQ ID NO:18 and fragments of SEQ ID NO:18.

In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

Applicant is invited to limit the claimed fragment to consisting of SEQ ID NO: 18.

10. Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of an antibody specifically binds to the amino acid sequence of SEQ I NO:18; however, applicant is not in possession of any antibody binding to any polypeptide part or any antibody to any peptide substantially depicted in SEQ ID NO:18. As the specification includes any substitution, addition, or deletion as long as the polypeptide maintain similar biological activity of $PGI_2$, the possible combinations of peptides encompassed in the claimed invention is out-numbered.
Consequently, conception in either case cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 13-15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Weksler (J. Cell. Physiology, 1990, 142:514-522, IDS reference).

Weksler teaches monoclonal murine antibody to anti-$PGI_2$ synthase (p. 1990, under material).

As claimed limitation of "substantially depicted" does not limit to SEQ ID NO:18, the antibody to anti-$PGI_2$ synthase would encompass claimed whole or part epitopes. Thus, the reference teaching anticipates the claimed invention.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyata et al. (Biochem. Biophy. Res Comm. 1994, 200; 1728-1734) in view of Campbell (Monoclonal Antibody Technology, 1984, Elsevier Science Publisher, pp. 1-32).

Miyata et al. disclose the sequence information of human prostycyclin synthase.

Miyata et al. do not teach a polyclonal or monoclonal antibody of human prostycyclin synthase.

However, Campbell teaches advantages between polyclonal and monoclonal antibodies and the applications of monoclonal antibodies in diagnosis and treatment (p. 5, 17). Campbell further teaches making antibodies to any known antigen is customary practice even without the clear objective for the application (P. 29).

Therefore, one of the ordinary skill in the art would have been motivated to make both polyclonal and monoclonal antibodies to use the antibodies for the purpose of diagnosis and treatment.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 13-20 are provisionally rejected under the judicially created doctrine of double patenting over pending claims 25-32 of copending Application No. 10/608,53. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass an antibody to human prostacyclin synthase.

17. No claims are allowable.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
August 11, 2005

Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600